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#16

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/445,803	12/13/1999	MARIO T. PHILIPP	TUL2AUSA	1398

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EXAMINER

SWARTZ, RODNEY P

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 02/21/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/445,803

Applicant(s)

PHILIPP, MARIO T.

Examiner

Rodney P. Swartz, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10December2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11,81 and 104-108 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 11,16,17,19,21,22,31-33,38,47-49,51-53,66,68-72,81,82,84-90,97-99,101,103-108 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 13.

- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 11,16,17,19,21,22,31-33,38,47-49,51-53,66,68-72,81,82,84-90,97-99,101 and 103-108.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 16,17,19,21,22,31-33,38,47-49,51-53,66,68-72,82,84-90,97-99,101 and 103.

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DETAILED ACTION

1. Applicant's Response to Office Action, received 10December2002, paper#11, is acknowledged. Claims 10, 12, 13, 39, 67, 83, 100 and 102 have been canceled. Claim 81 has been amended.

The numbering of new claims 103-107 requested to be added is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Therefore, misnumbered claims 103-107 have been renumbered 104-108.

2. Currently, claims 11, 16, 17, 19, 21, 22, 31-33, 38, 47-49, 51-53, 66, 68-72, 81, 82, 84-90, and 97-99, 101, and 103-108 are pending. Claims 16, 17, 19, 21, 22, 31-33, 38, 47-49, 51-53, 66, 68-72, 82, 84-90, 97-99, 101, and 103 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

3. Claims 11, 81, and 104-108 are under consideration.

Rejections Withdrawn/Moot

4. The rejection of claims 10, 12, and 13 under 35 U.S.C. 112, second paragraph, as being indefinite for "the P39.5 protein" is moot in light of the cancellation of the claims.

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5. The rejection of claims 10, 12, and 13 under 35 U.S.C. 112, second paragraph, lack of antecedent basis for the limitation "the" P39.5 protein is moot in light of the cancellation of the claims.
6. The rejection of claims 100 under 35 U.S.C. 112, first paragraph, scope of enablement for detection using other fragments, homologs, analogs, or fusion proteins of P39.5 or P7-1 is moot in light of the cancellation of the claim.
7. The rejection of claim 83 under 35 U.S.C. 112, second paragraph, as being indefinite, is moot in light of the cancellation of the claim.
8. The rejection of claim 102 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, is moot in light of the cancellation of the claim.
9. The rejection of claim 39 under 35 U.S.C. 112, first paragraph, written description, is moot in light of the cancellation of the claim.
10. The rejection of claims 10, 12, 13, 39, 67, 83, 100, and 102 under 35 U.S.C. 102(b) as being anticipated by Zhang et al (*Cell*, 89:275-285, April, 1997) is moot in light of the cancellation of the claims.

Rejections Maintained

11. The rejection of claim 11 under 35 U.S.C. 112, second paragraph, as being indefinite for "the P39.5 protein" is maintained for reasons of record.
12. The rejection of claim 11 under 35 U.S.C. 112, second paragraph, lack of antecedent basis for the limitation "the" P39.5 protein is maintained for reasons of record.

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13. The rejection of claim 81 (as newly amended) under 35 U.S.C. 112, first paragraph, scope of enablement for detection using other fragments, homologs, analogs, or fusion proteins of P39.5 or P7-1 is maintained.

Applicants argue that the amendment of claim 81 and addition of new claims 104-108 obviate the rejection.

The examiner has considered applicants' argument, but does not find it persuasive. Newly amended claim 81 is drawn to a kit comprising a protein or a peptide of claim 104. New claim 104 is drawn to a protein or peptide that reacts with antibodies to the causative agent of Lyme Disease wherein said protein or peptide is (g) an amino sequence that differs from sequence of (a) through (f) by up to four codon changes in the nucleic acid sequences encoding the amino acid sequence.

There is no requirement for the codon changes to be at any particular position in the DNA encoding SEQ ID NO:2, 3, 7, 11, 14, or fragments thereof. Therefore, the ≥ 4 changes in such DNA may result in an entirely new unknown amino acid sequence. The specification is silent concerning such a peptide or protein, nor does the specification give sufficient guidance to chose which entirely new unknown amino acid sequence(s) would react with antibodies to the causative agent of Lyme Disease.

14. The rejection of claim 81 (as newly amended) under 35 U.S.C. 112, second paragraph, as being indefinite, is maintained.

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Applicants argue that the amendment of claim 81 and addition of new claims 104-108 obviate the rejection.

The examiner has considered applicants' argument, but does not find it persuasive. Newly amended claim 81 is drawn to a kit comprising a protein or a peptide of claim 104. New claim 104 is drawn to a protein or peptide that reacts with antibodies to the causative agent of Lyme Disease wherein said protein or peptide is (g) an amino sequence that differs from sequence of (a) through (f) by up to four codon changes in the nucleic acid sequences encoding the amino acid sequence. It is unclear what is the identity of the new amino sequence because of the indefiniteness of where the codons changes occur.

15. The rejection of claims 11 and 81 and now newly added claims 104-108 under 35 U.S.C. 102 as being anticipated by Zhang et al (*Cell*, 89:275-285, April, 1997) is maintained.

Newly added claims 104-108 would have been rejected for the same reasons as 11 and 81 if claims 104-108 had been presented prior. Therefore, claims 104-108 are included in the rejection.

The examiner notes that the initial rejection was incorrectly listed in the Office Action as being put forth under 35 U.S.C. 102(b), when in actuality, the qualifies under 35 U.S.C. 102(a). Applicants correctly identified that the reference actually qualifies under 35 U.S.C. 102(a) and directed their arguments appropriately.

Applicants argue that the submitted Declaration under Rule 131 provides evidence of conception of the claimed invention prior to the publication date of the reference, 18April1997.

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Patent Rules § 1.131 Affidavit or declaration of prior invention recites:

- (a) When any claim of an application or a patent under reexamination is rejected, the inventor of the subject matter of the rejected claim, the owner of the patent under reexamination, or the party qualified under §§ 1.42, 1.43, or 1.47, may submit an appropriate oath or declaration to establish invention of the subject matter of the rejected claim prior to the effective date of the reference or activity on which the rejection is based. The effective date of a U.S. patent, U.S. patent application publication, or international application publication under PCT Article 21(2) is the earlier of its publication date or date that it is effective as a reference under 35 U.S.C. 102(e). Prior invention may not be established under this section in any country other than the United States, a NAFTA country, or a WTO member country. Prior invention may not be established under this section before December 8, 1993, in a NAFTA country other than the United States, or before January 1, 1996, in a WTO member country other than a NAFTA country. Prior invention may not be established under this section if either: (1) The rejection is based upon a U.S. patent or U.S. patent application publication of a pending or patented application to another or others which claims the same patentable invention as defined in § 1.601(n); or (2) The rejection is based upon a statutory bar.
- (b) The showing of facts shall be such, in character and weight, as to establish reduction to practice prior to the effective date of the reference, or conception of the invention prior to the effective date of the reference coupled with due diligence from prior to said date to a subsequent reduction to practice or to the filing of the application. Original exhibits of drawings or records, or photocopies thereof, must accompany and form part of the affidavit or declaration or their absence satisfactorily explained.

While the submitted Declaration indicates a date of completion of the invention was in either a NAFTA or WTO member country, or the United States prior to the effective date of the

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cited reference, the Declaration is defective in that it contains no direct **statement** stating that the reduction to practice/completion of the invention was in a NAFTA or WTO member country, or the United States prior to the effective date of the cited reference.

New Objections/Rejections Necessitated by Amendment

16. Claim 11 is objected to because it depends from a canceled claim.

Claim Rejections - 35 USC § 112

17. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

18. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

19. Claims 104-108 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are directed to an amino acid sequence that differs from a sequence of a-f by up to four codon changes in the nucleic acid sequence encoding the amino acid sequence.

The claims are indefinite because the change in even one codon may shift the reading frame, resulting in an unknown amino acid sequence.

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The claims are also indefinite because it is unclear what is meant by the term "reacts with antibodies". It is suggested that the claims be amended to recite "peptide that binds with antibodies".

Conclusion

20. Claims 11, 81, and 104-108 are finally rejected.

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


22. This application contains claims 16, 17, 19, 21, 22, 31-33, 38, 47-49, 51-53, 66, 68-72, 82, 84-90, 97-99, 101, and 103 drawn to a nonelected invention. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

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23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-0196.


RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER
Art Unit 1645

February 20, 2003